



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-3319]

Framework for the Use of Digital Health Technologies in Drug and Biological Product Development; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the publication of a digital health technology (DHT) framework by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research. This framework is entitled “Framework for the Use of Digital Health Technologies in Drug and Biological Product Development.” This fulfills an FDA commitment under the seventh iteration of the Prescription Drug User Fee Act (PDUFA VII) reauthorization, incorporated as part of the FDA User Fee Reauthorization Act of 2022.

DATES: Either electronic or written comments on the framework must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2022-N-3319 for "Framework for the Use of Digital Health Technologies in Drug and Biological Product Development." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly

viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Ryan Robinson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3342, Silver Spring, MD 20993-0002, 240-402-9756, [Ryan.Robinson1@fda.hhs.gov](mailto:Ryan.Robinson1@fda.hhs.gov); or Diane

Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

## SUPPLEMENTARY INFORMATION:

### I. Background

In connection with PDUFA VII, incorporated as part of the FDA User Fee Reauthorization Act of 2022, FDA committed to establish a framework that will guide the use of DHT-derived data in regulatory decision-making for drug and biological products. FDA is publishing the “Framework for the Use of Digital Health Technologies in Drug and Biological Product Development” to satisfy the PDUFA VII commitment.

DHTs may provide opportunities for more efficient drug development. DHTs and DHT-derived data can be important tools in supporting timely access to safe, effective, and innovative new medicines for patients. Despite the potential advantages of DHTs, many challenges arise when incorporating DHTs and DHT-derived data into regulatory decision-making. This framework outlines a multifaceted approach to collaboratively address these challenges with stakeholders. Through these joint efforts, FDA intends to advance the development of drugs and promote the public health.

The framework will guide activities such as (1) defining objectives for workshops and demonstration projects, (2) developing methodologies for evaluating DHTs proposed as measuring key (primary or important secondary) endpoints or other important measures (e.g., for safety monitoring or baseline characterization) in clinical trials, (3) managing submissions with extensive and continuous data (e.g., in order to develop acceptable approaches to capture adverse events), and (4) developing a standardized process for data management and analysis of large datasets from DHTs.

### II. Electronic Access

Persons with access to the internet may obtain the “Framework for the Use of Digital Health Technologies in Drug and Biological Product Development” at

<https://www.fda.gov/science-research/science-and-research-special-topics/digital-health-technologies-dhts-drug-development>.

Dated: March 20, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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